UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL NO. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Subcategory Docket: 06-CV-11337-PBS
THIS DOCUMENT RELATES TO	)	Judge Patti B. Saris
U.S. ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al., No. 06-CV-11337-PBS	)	Magistrate Judge Marianne B. Bowler

ABBOTT LABORATORIES INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT

Dated: June 26, 2009

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INTRODUCTION

In this extraordinary lawsuit, the Government seeks to recover from Abbott more than $107 million that the Government, through the Medicare and Medicaid programs, paid to healthcare providers between 1991 and 2001. Although this Court is familiar with litigation concerning AWP and the alleged inflation of Government payments, this case is unique. For the first time, a jury in the Southern District of Florida will hear detailed, exhaustive evidence about the policy choices that State and Federal Governments repeatedly made about drug pricing and provider payments. More particularly, the jury will learn that in the area of home infusion in particular, Medicare and Medicaid knowingly paid a profit on drug costs to offset inadequate (or non-existent) dispensing fees. That evidence yields but one conclusion: The payments made to providers for the four Abbott home infusion products at issue (Vancomycin, saline, dextrose, and sterile water) were not caused by any fraud by Abbott. Rather, they resulted from deliberate, informed choices the Government made to ensure that the elderly and the poor had equal access to healthcare services.

Abbott is confident that a jury will reject the Government's claims entirely. Abbott also recognizes that the underlying questions of liability in this case are far too factually complex to be amenable to summary judgment. Accordingly, Abbott does not seek summary judgment as to liability on the Government's False Claims Act ("FCA") claims, but instead asks the Court to send those claims to trial.

Still, this case presents several narrow, but significant, issues that can and should be pared away before the matter is sent back for trial to the originating court. To the extent the Government's proof is too scant, or even non-existent, the Court should enter judgment for Abbott as to:

- Damages for FCA claims relating to payments that were based on something other

than a reported Abbott price; damages for claims supported only by inadmissible expert "extrapolation," rather than actual evidence; damages for claims paid based on an AWP proxy (as this Court held in its Massachusetts decision); and damages for FCA claims for Ohio Medicaid, which the Government has abandoned;

- Damages for FCA claims after Ven-A-Care's complaints naming the four Abbott drugs at issue were filed;
- The Government's claims relating to Abbott's former Home Infusion Services business, and the Government's untimely unjust enrichment claims; and
- All FCA claims accruing prior to March 17, 2000.

First, as to damages, the Government's 11-year delay in unsealing this case against Abbott has left Abbott in an untenable situation. This Court has rightly made clear in prior rulings that damages are not simply presumed in FCA litigation. Instead, the Government must establish damages on a drug-by-drug, program-by-program, state-by-state basis. The Government cannot do that here because it took no steps to preserve relevant evidence while this case languished under seal for over a decade. The data necessary to prove actual damages is, in large part, gone. That leaves the Government with no means to show *how it actually paid* for the Abbott products at issue. Indeed, as to the Medicaid programs for 39 states, the Government seeks alleged overpayments of more than $27 million for Abbott's four products, *but does not offer a single shred of actual claims data* to support its calculations. The Government has a similar problem for Medicare, where Carriers were allowed to destroy the pricing arrays that determined payments for all four Abbott products at issue here.

The Government has tried to paper over this gap with the testimony of its damages expert, Dr. Duggan, but the effort falls flat. Because the Government could not give Dr. Duggan complete data for the ten states and handful of Carriers he examined, Dr. Duggan "extrapolated" findings from the bits of data he received in an unsuccessful effort to fill the gaps. And he proceeded to further "extrapolate" his findings out to 39 other states and all Carriers for which he

examined no data at all, or ignored the data he had for some of these states and Carriers, to inflate the Government's damages figures. This so-called extrapolation is not based on any statistically valid sample, but is more akin to biased guess-work which ignores the clear holdings of this Court in related AWP litigation.

Some examples are illustrative. As to Medicaid, Dr. Duggan admits that he made *no effort* at all to determine whether a particular state based any payments to providers on a reported price (AWP, WAC, or DP), as opposed to some other benchmark (like a MAC, FUL, U&C), or a specially-set payment for home infusion products. These alternative payment mechanisms, of course, may have had nothing to do with Abbott's price reporting. Likewise, as to Medicare, Dr. Duggan did nothing to establish whether any particular Carrier considered Abbott's prices in setting a J-code payment level. Given Dr. Duggan's failure to correlate his findings to Abbott's actual conduct, it is not surprising that he does not even attempt to offer a "confidence interval," or any other statistical metric that would allow the Court to evaluate the reliability of his conclusions. Indeed, given the nature of this work, the Court should have no confidence whatsoever in his conclusions, as discussed in detail in Abbott Laboratories Inc.'s Memorandum in Support of its Motion *In Limine* to Exclude Certain Opinions Proffered by Mark G. Duggan, Ph.D, filed concurrently with this motion.[1] And because he provides the Government's only evidence for these damages, these damages should not go to a jury.

Second, the Government's damages claims falter because, after Ven-A-Care filed its complaints naming the Abbott products at issue here and describing in detail the alleged "spreads" for those products, the Government had full knowledge of Abbott's alleged pricing

[1] Abbott has filed this motion because excluding certain of Dr. Duggan's opinions provides another ground to grant Abbott's motion for summary judgment on certain classes of allegedly false claims.

conduct. At a minimum, the FCA does not allow the Government to recover actual damages where, as here, the Government had knowledge of the alleged falsity of the claims, yet paid them anyway. When that happens, actual damages are not incurred "because of the act of" the defendant, as required by statute.

Damages should stop accruing at the filing of the complaints for the additional reason that the Government's excessive delay in unsealing has violated Abbott's Due Process rights. The Government's post-complaint actual damages are directly traceable to its decision to keep the complaint under seal, thus depriving Abbott of notice that it faced liability for its ongoing business activities. Cutting off actual damages is an appropriate remedy for that Due Process violation. To allow otherwise would "permit plaintiffs who know of the defendant's pattern of activity simply to wait, 'sleeping on their rights,' as the pattern continues and treble damages accumulate, perhaps bringing suit only long after the 'memories of witnesses have faded or evidence is lost.'" *Klehr v. A.O. Smith Corp.*, 521 U.S. 179, 186-88 (1997) (quoting *Wilson v. Garcia*, 471 U.S. 261, 271 (1985)).

Third, neither the Government's unjust enrichment claim, nor its allegations related to Abbott's former Home Infusion Services business, relate back to Ven-A-Care's complaints. Those untimely claims should be dismissed. And *finally*, because the Government's complaint-in-intervention cannot relate back to Ven-A-Care's complaints, over which this Court lacked jurisdiction, all FCA claims accruing prior to March 17, 2000 should be dismissed as untimely.

STATEMENT OF FACTS

A. The Seal Period (June 23, 1995 – March 17, 2006).

This motion does not require the Court to wrestle with disputed facts regarding what the Government knew about the extent of spreads for the drugs at issue, or when it knew it, for liability purposes. The jury will do that. This motion is drawn to a narrower, undisputed (and

undisputable) point: By no later than June 23, 1995, when Ven-A-Care filed its first under-seal complaint in this case, the Government was fully informed of allegedly fraudulent pricing inflation on dozens of specific infusion and injectable pharmaceutical products. (SOF ¶¶ 2-5.) This includes the three major products at issue in this case (Vancomycin, sodium chloride, and dextrose); the spreads for these products were detailed in Ven-A-Care's complaint. (*Id.* ¶¶ 3-4.)[2]

The highest levels of CMS learned of Ven-A-Care's allegations within months of the complaint being filed. The details were set forth in a September 14, 1995 meeting attended by Ven-A-Care, the Department of Justice ("DOJ"), and senior officials from the Health Care Financing Administration ("HCFA" or "CMS") and the Office of Inspector General ("OIG"). (*Id.* ¶ 6.) Participants discussed "The False AWP Multi-Billion-Dollar Machine" and the impact on the Medicaid and Medicare programs of allegedly false AWPs for infusion, injectable, and inhalation drugs, including specifically Abbott's Vancomycin. (*Id.* ¶¶ 6-7.)[3] If the pricing inflation described in Ven-A-Care's complaint was not already known to the Government by then (and extensive evidence, which Abbott will present at trial, demonstrates that it was, *see id.* ¶¶ 52-53, 55-59), CMS cannot deny that it was on notice afterward.

While the Government mulled whether to intervene in this case, it continued to direct or allow these programs to base payments on the very same compendia prices it now complains were "fraudulent." Even the Relator expressed dismay about the Government's inaction. For example, in an October 2, 1996 letter, Ven-A-Care provided CMS with catalogs containing

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[2] The fourth drug, sterile water, first appeared in Ven-A-Care's August 12, 1997 Second Amended Complaint. (*Id.* ¶ 15.)

[3] Ven-A-Care's allegations were also made known to state Medicaid programs, including at a March 1998 meeting of National Association of Medicaid Fraud Control Units ("NAMFCU") attended by representatives of nearly every state. *See Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 151 (D. Mass. 2008); (*see also* SOF ¶ 66 (detailing earlier meetings with state officials, starting in the first half of 1997).)

marketplace prices for infusion, injectable, and inhalation drugs (including each of the four products at issue here), complaining that the Government's lack of "meaningful action" with this information was "disconcerting" and "potentially the source of major embarrassment to both your Agency and to the Administration." (*Id.* ¶¶ 8-9.)

Medicare and Medicaid deliberately chose to continue to use the allegedly fraudulent prices published for Abbott drugs during this time; they were not misled or stymied by a lack of alternatives. Medicare did so because Congress rejected Administration efforts to base payment on actual acquisition cost. (SOF ¶¶ 41-42.) Starting in 1999 (seven years before this case was unsealed), the DOJ itself attempted to change the policy of relying upon compendia AWPs to compute reimbursement for many of the infusion, injectable, and inhalation products at issue in Ven-A-Care's complaints by working with NAMFCU and First Databank to publish "more accurate wholesale prices" for these products. (*Id.* ¶¶ 33-35, 45-46.) The DOJ shared these prices with the states and also sought to implement them in Medicare after receiving a "revised" legal opinion from the Department of Health and Human Services's Office of General Counsel on their use.[4] (*Id.* ¶¶ 35-36, 46.)

Recognizing that slashing the "spread" on drugs without also considering any necessary, off-setting increases in administrative fees paid to providers would cause an upheaval, *Congress* moved swiftly to block their use in Medicare.[5] (*Id.* ¶ 48.) Similarly, for Medicaid, with full

[4] When Abbott asked for a copy of both the revised and original legal opinions—referenced in documents the Government withheld under the deliberative process privilege until well after the end of fact discovery—the DOJ indicated: "[W]e have been unable to locate any OGC document containing this opinion and, based on our inquiries, now believe that the referenced opinion was conveyed orally by OGC staff." (*Id.* ¶ 46.)

[5] Even when Congress developed the ASP methodology in the Medicare Modernization Act of 2003, it specifically maintained the 95% of AWP methodology for "infusion drugs administered through durable medical equipment." (*Id.* ¶ 49.) Thomas Scully, the CMS Administrator at the time, testified that this exemption from the new ASP methodology was intended to "freeze" in a level of "cross-subsidy." (*Id.*) Vancomycin was typically administered through durable medical equipment during the relevant period.

knowledge that they were paying healthcare providers far more than their actual acquisition cost for drugs, most states rejected or quickly stopped using DOJ's lower prices and chose to continue using "inflated" AWPs for drug payments. (*Id.* ¶¶ 36-37.) Missouri, for example, stopped using the DOJ prices because its $4.09 dispensing fee "was not designed to cover these drugs" and "providers threatened to cease services due to insufficient dispensing fees." (*Id.* ¶ 38.) Thus, even after the Government was aware of the alleged fraud at issue here, the Medicaid and Medicare programs continued using compendia prices for these drugs as a policy matter. That was the Government's deliberate choice, not Abbott's fraud. *Mylan Labs.*, 608 F. Supp. 2d at 152.

B. The Government's Intervention, First Amended Complaint, And Current Damage Computations (March 17, 2006 – Present).

On March 17, 2006, the Government finally decided to intervene against Abbott in this case, attempting to accomplish through the court system what Congress and most Medicaid programs had rejected half a decade earlier: the implementation of lower pricing on injectable and infusion drug products with no corresponding increase in dispensing or administrative payments. A year later, on November 7, 2007, the DOJ sought to up the stakes against Abbott, filing a First Amended Complaint. The DOJ attempted to add to the case a new drug, Acyclovir, as well as 27 paragraphs of allegations concerning Abbott's former Home Infusion Services business. (This Court ruled the Government could not add claims relating to Acyclovir, *see* Dkt. No. 5143.) The allegations concerning Home Infusion Services, which the Government incorporated by reference into its existing causes of action, added entirely new facts and legal theories to the litigation.

The operative complaint now contains three causes of action—two under the FCA and one for unjust enrichment—and seeks recovery relating to over 13 million allegedly false claims

paid by the Medicaid and Medicare programs for the four Abbott products during the 1991 through 2001 time period. (SOF ¶ 82.) The Government relies on testimony from Professor Mark G. Duggan, a Professor in the Department of Economics at the University of Maryland, to prove causation and compute alleged actual damages. (*Id.* ¶ 79.) Dr. Duggan purports to calculate a "difference" of $107.1 million, which he describes as the

> difference between (1) what the federal government reimbursed for certain pharmaceutical products provided to Medicaid and Medicare recipients during the eleven-year period 1991 and 2001 and (2) what the federal government would have reimbursed for the same products during the same time period if prices reflective of the actual prices at which Abbott was transacting business had been used for the AWP, WAC, and Direct Price of Abbott products.

(*Id.* ¶ 82.) Of this $107.1 million "difference," $64.7 million relates to Medicaid, while $42.4 million relates to Medicare. (*Id.*) The DOJ refers to this "difference" as a damages calculation.

To say there is a "difference" between what Medicare and Medicaid paid and what they could have paid is not, in fact, to establish "damages" in this case. Dr. Duggan's "difference" calculation is entirely mechanical and untethered from the extensive evidentiary record developed in this case. He specifically ignored evidence indicating that:

- Many states used payment benchmarks which did not depend upon any reported price for an Abbott drug (*id.* ¶ 21);
- Medicaid and Medicare officials knowingly paid a margin on drug ingredient costs to provide a profit to providers, subsidize inadequate dispensing fees, and assure continued access to care—particularly for the type of drugs at issue here (*id.* ¶¶ 21, 23-27, 49, 162-165);
- State and federal officials believed and understood that the term "average wholesale price" in state statutes and the Medicare Act referred to published prices that they knew bore no relationship to market prices for the type of drugs at issue here (*id.* ¶¶ 50-61); and
- Most of the states and Medicare knowingly and intentionally rejected a previous DOJ attempt—the "DOJ AWPs"—to impose revised prices akin to the prices Dr. Duggan uses here. (*Id.* ¶¶ 36-38.)

Critically, Dr. Duggan did not have or use the detailed claims data (Medicaid) or pricing arrays (Medicare) necessary to determine how, if at all, prices reported in compendia for Abbott drugs actually impacted payments on many of the allegedly false claims at issue. Instead, he reviewed claims data from a mere ten states (none of which was complete for the entire damages period), and arrays from a handful of Medicare Carriers, and then purported to extrapolate his findings from that limited data to the rest of the country. In so doing, Dr. Duggan admittedly did *nothing* to determine whether the 39 states and myriad Carriers—as to which he examined no data or arrays at all—ever based their payments on Abbott's reported prices (as opposed to a MAC, FUL, U&C, or some other price). It is this house of cards that should not survive for trial.

STANDARD OF REVIEW

Summary judgment is appropriate where, as here, "'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law.'" *Barbour v. Dynamics Research Corp.*, 63 F.3d 32, 36-37 (1st Cir. 1995) (quoting Fed. R. Civ. P. 56(c)); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). An "issue is 'genuine' for purposes of summary judgment" only "if the evidence is such that a reasonable jury could return a verdict for the nonmoving party, and a 'material fact' is one which might affect the outcome of the suit under the governing law." *Carcieri v. Norton*, 398 F.3d 22, 29 (1st Cir. 2005). Summary judgment "may be sought and entered on any part of a case." *Gore v. Trs. of Deerfield Acad.*, 385 F. Supp. 2d 65, 68 (D. Mass. 2005) (citing Fed. R. Civ. P. 56(b)).

ARGUMENT

I. THE COURT SHOULD GRANT SUMMARY JUDGMENT AS TO DAMAGES ON CERTAIN CLASSES OF ALLEGEDLY FALSE CLAIMS.

Actual damages under the FCA cannot be recovered when they are "remote," "speculative," "hypothetical," or otherwise "not within the realm of reasonable certainty." *U.S. ex rel. Ervin & Assocs., Inc. v. Hamilton Sec. Group, Inc.*, 370 F. Supp. 2d 18, 55 (D.D.C. 2005). Courts must be especially vigilant as to proof of damages where, as here, the statute at issue provides for trebling of actual damages. *See Euromodas v. Zanella*, 368 F.3d 11, 17 n.5 (1st Cir. 2004) (noting that courts have "limit[ed] the inferences [that may be drawn] from ambiguous evidence" in antitrust cases because they "expose[] a defendant to treble damages"); Breckinridge L. Wilcox & Jefferson M. Gray, *Extrapolation of Damages and Penalties in Fraud Cases: A Slippery Slope in FCA Actions, Business Crimes Bulletin* (Dec. 2000) ("[T]he FCA's provisions for multiple damages and penalties mean that the financial impact of any claims erroneously treated as improper under the extrapolation will be greatly magnified.").

Here, despite having 11 years of pre-unsealing one-way discovery against Abbott, and three years of discovery in this case, the Government has failed to adduce damages evidence to support most of the claims within its two FCA counts. Indeed, for many, the Government *has not even tried* to prove damages consistent with this Court's prior rulings. This lack of evidence is fatal to the Government's broadly-asserted right of recovery. Without such evidence, there is no reason to "needlessly prolong[ ] the litigation, only to [permit the Government to] lose at trial due to the same dearth of admissible evidence." *Maier-Schule GMC, Inc. v. General Motors Corp.*, 154 F.R.D. 47, 59 (W.D.N.Y. 1994). Rather, summary judgment on actual damages for those claims should be granted, now, to Abbott. *See* Fed. R. Civ. P. 56(b) & (d); *Masso v. United Parcel Serv. of Am., Inc.*, 884 F. Supp. 610, 620 n.8 (D. Mass. 1995) ("Defendants may,

of course, seek summary judgment, in whole or in part, to the extent that [plaintiff] cannot recover damages."); *Bonacorso Const. v. Master Builders, Inc.*, No. 87-1827, 1991 WL 72796, at *9-10 (D. Mass. Apr. 24, 1991) (granting summary judgment as to damages).[6]

The Government improperly pursues actual damages for the following:

- Claims where payment was not based on a published compendia price;
- Claims for which the Government's only evidence is inadmissible expert testimony attempting to extrapolate incomplete data from ten states and a handful of Medicare contractors to the rest of the country;
- Claims paid by Medicaid programs based on an AWP proxy for WAC; and
- Claims for Ohio Medicaid, which the Government has abandoned.

Dismissal of these categories of claims would provide much-needed pruning of this massive 50-state Medicaid and Medicare case for trial, saving the Court (and the jury) valuable time. Each category is discussed in turn.

A. The Court Should Grant Summary Judgment As To All Claims Paid By Medicaid Programs Or Medicare That Were Not Based On A Published Compendia Price.

All of the allegedly false claims at issue for Abbott involve multiple-source drugs. The Government's liability theory for the FCA counts as to these drugs assumes a causal link between the publication of an allegedly false price (AWPs, WACs, and DPs reported by compendia), on the one hand, and the Government's injury (*i.e.*, that the claim was paid based on the allegedly false price), on the other. To the extent that Medicaid and Medicare did not pay based on a compendia-reported price—as is true for many of the payments at issue in this case

[6] Summary judgment on damages for Abbott on these claims is appropriate even though issues of fact clearly exist for a jury to consider as to liability. *See Bonacorso*, 1991 WL 72796, at *9-10 (granting summary judgment to plaintiff on liability, but summary judgment to defendant on damages); *Maier-Schule GMC*, 154 F.R.D. at 52-61 ("[T]his Court has found numerous cases where a court granted a defendant summary judgment on some or all of plaintiff's claims for damages despite the fact that the court determined that the plaintiff presented otherwise meritorious claims.") (citing cases).

where the state MAC, U&C, or some other basis was used—the Government's theory is invalid.

This Court has consistently ruled in AWP litigation that, to recover damages for claims involving generic drugs, plaintiffs must show that the claims were, in fact, paid based on a published price. In the California AWP litigation, for example, the Court dismissed the complaint "as it relates to the drugs reimbursed on a MAIC methodology" (California's state MAC) because there was no causal link between the MAIC prices and the allegedly false prices reported by defendants. *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F. Supp. 2d 164, 180 (D. Mass. 2007); *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 91 (D. Mass. 2005) (holding, for third party payors in the non-Medicare Part B context, that "generics will be considered only to the extent the price in the contract between the TPP and physician is expressly predicated on AWP"). Similarly, in the Massachusetts AWP litigation, the Court noted that Massachusetts's statutory scheme also considered MULs (Massachusetts's state MAC), FULs, and provider charges in determining payment amounts. *See Mylan Labs.*, 608 F. Supp. 2d at 148 n.4 (D. Mass. 2008).[7] These rulings, and their rationale, require that damages for many of the claims at issue in the Government's FCA counts be adjudicated in Abbott's favor at this stage.

First, many of the Medicaid claims were paid based on a state MAC.[8] (SOF ¶¶ 99, 103, 105, 107-108.) The Government offers no evidence concerning how, if at all, Abbott's allegedly inflated prices impacted the MAC levels set by the states. (*Id.* ¶¶ 121-24.) Indeed, the MAC pricing instituted by many states was not affected at all by compendia prices. (*Id.* ¶¶ 28-32.)

[7] The Court held open the possibility of recovery on claims reimbursed on the basis of a MUL or FUL, but only to the extent that defendants' reported prices actually "formed the basis for the drug's FUL and MUL." *Id.*

[8] For reasons which have never been adequately explained, CMS did not establish Federal Upper Limits ("FULs") on any of the Complaint NDCs. (SOF ¶ 127.)

Yet, the Government's damage model includes damages on claims paid based on these MACs—inflating damages. (*Id.* ¶ 124.) The Government's damages case glosses over the use of MACs, as shown by its use of Myers & Stauffer to determine how the 50 Medicaid programs reimbursed drugs, without asking that firm to identify which states implemented MACs on the Complaint NDCs (and, if so, when), or how those MAC levels were determined. (*Id.* ¶¶ 120-123.)

To permit the Government to characterize as an illegal "overpayment" any difference between a state MAC and a revised AWP-based allowable amount—particularly where there is no link between the reported price and the MAC—would overturn state policy on what payment levels were appropriate and fair under the circumstances. Extensive record evidence makes clear that MAC pricing (and pricing in general) was influenced by policy determinations and a give-and-take with providers to come up with levels that were fair under the circumstances. (SOF ¶¶ 29-32.) The Government's approach completely ignores price margins knowingly and intentionally allowed to providers by many states' MAC pricing. (*Id.* ¶¶ 29-32, 125-126.)

For example, the Myers & Stauffer analysis prepared for this litigation asserts as follows in regard to Minnesota's approach to establishing MACs:

> SMACs are based on an informal survey of a few retail pharmacies that have agreed to share their costs. *The State tries to include an average profit of about $7.00 for each prescription using SMAC.* This $7 includes the $3.65 dispensing fee. . . .

(*Id.* ¶ 125.) (emphasis added). Yet the Government's damages expert (Dr. Duggan) admitted that he did not consider such evidence and that he was not aware of it. (*Id.*) He even agreed that it was possible that "state Medicaid programs and providers engaged in a process where they looked at proposed MAC levels, considered all the issues that might go into drug payment policy and decided on a MAC level that was fair and workable." (*Id.* ¶ 126.)

Second, Dr. Duggan's work shows that a considerable portion of the Medicaid and

Medicare claims at issue were reimbursed based on U&C. (*Id.* ¶ 130.) As with MACs, it is undisputed that the Government's model includes damages on claims paid based on provider charges. (*Id.* ¶ 149.) The Government has made no effort to separate out such claims from its damages calculation, even though they clearly bear no imprimatur of Abbott's reported prices.

Finally, many states used alternative reimbursement methods for home infusion and compounded drugs. For example, while many states (particularly high expenditure states) reimbursed prescriptions for labor-intensive intravenous and compounded drugs similar to simple pill prescriptions (allowing the margin on drug cost to compensate for the additional dispensing cost), other states developed unique methods that provided additional reimbursement. (*Id.* ¶ 141.) Evidence indicates that many of these unique methods deliberately paid a margin on ingredient cost for intravenous drugs.

An article published in a 1987 issue of the *Medicaid Pharmacy Bulletin*, "Medicaid Reimbursement for the Pharmacy Component of Home I.V. Therapy," described examples of this phenomenon. (*Id.* ¶ 21.) The *Bulletin*, after acknowledging that the dispensing of intravenous prescriptions was considerably more complex than typical retail prescriptions, noted that Oregon based its reimbursement for intravenous prescriptions at 80% of usual and customary charges, that Montana paid the lower of U&C or 2 ½ times the cost of ingredients plus a dispensing fee, and that Massachusetts paid a "mark up" on the drug depending on the cost of the drug (lower priced products received a higher mark up.)[9] (*Id.*) Some states have testified that they permitted or were aware that their policies paid a margin on ingredient cost, and that this margin served to compensate for the higher cost to administer intravenous and compounded

[9] The *Bulletin* was published between 1987 and the mid-1990s "to assist the Medicaid pharmacy community in keeping abreast of the latest program management practices and developments in health care policy that affect Medicaid pharmacy." (*Id.* ¶ 21.) State officials found the Bulletin to be a valuable source of data.

drugs. (*Id.* ¶ 27.) This sentiment is contained in numerous contemporaneous reports prepared by Myers & Stauffer for state Medicaid programs. (*Id.* ¶¶ 23-26.)

Other states appear to have used minimum reimbursement levels for compounded drugs based on usual and customary charges. For example, the Myers & Stauffer summary prepared for Dr. Duggan for Iowa indicates that "Iowa Medicaid allowed pharmacies to bill for compounded claims using the NDC of one of the active ingredients, adjusting the price to the full compound price online for those claims $30 and under." (*Id.* ¶ 22.) Similarly, in New York, the Myers & Stauffer summary indicates that "[r]eimbursement for each compound prescription is restricted to the usual and customary price charged to the general public for the total sum of the ingredients, up to the maximum reimbursable amount ($50.00) . . . ." (*Id.*) Because most of the Complaint NDCs were relatively inexpensive (often costing $2 or less), it is clear that the Government's claimed "damages" include payments that were deliberately designed to allow a margin on ingredients.

The Government will surely try to defend its flawed approach with an argument this Court already rejected in the California litigation: Had Abbott reported lower prices, those lower prices would have formed the basis of payment for states which used a "lower-of" methodology. (*See* Dkt. No. 2181 (Cal. 3/3/06 Br.) at 34-35 ("Even after 2002, when MAICs were not set on reported prices, the reimbursement formula always paid 'the lower of' MAIC, AWP, or other prices. Had Defendants' AWPs not been falsely inflated, they would often have been lower than the MAICs and would have set the reimbursement price.").) The Court's previous rejection of this argument was correct. *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 478 F. Supp. 2d at 180. The entire premise of the Government's case is that Abbott reported allegedly inflated prices in order to provide a kick-back to its Customers and increase its market share. (*See* SOF

¶ 3, Ex. B Opening ¶.) This theory collapses when a state does not base reimbursement on the reported price, such as when a state sets a MAC for all products within the particular drug class. In such cases, Abbott could not increase its market share by manipulating reported prices. And in any event, the Government has no evidence concerning how, if at all, Abbott's allegedly inflated prices impacted the MAC levels set by the states. (*Id.* ¶¶ 122-123.)

* * *

While much of this evidence raises critical issues outside the instant motion—indeed, issues that go to the heart of whether "false claims" have been submitted and paid in the first place—the key point for this motion is that neither the Government, nor its expert, even tried to grapple with the issues. They merely calculated "differences" for nearly every claim in the case, regardless whether those claims were paid based on a reported compendia price. *See* 31 U.S.C. § 3729(a) (allowing "damages which the Government sustains *because of* the act of" the defendant) (emphasis added). Without Dr. Duggan's flawed testimony, which should be excluded, the Government has no evidence to support these damages claims. And even if Dr. Duggan's work were admissible, it could not establish a genuine issue of material of fact as to damages for these claims. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 596 (1993) (noting that summary judgment remains available as one "means of attacking shaky but admissible evidence"). Consistent with its prior orders, the Court should not allow recovery of damages for any claims paid based on something other than a compendia-reported price.

B. The Court Should Grant Summary Judgment As To Damages On All Claims Where The Government Relied Exclusively On Flawed Expert Extrapolation, And Thus Lacks Sufficient Evidentiary Damages Support.

The Government's damages case also plainly contradicts the Court's precedents requiring a showing that the claims at issue were, in fact, paid based on a published price. As to Medicaid, the Government does not have or use the detailed claims data necessary to show how 39 state

Medicaid programs actually determined the payment amounts for the allegedly false claims at issue. (SOF ¶ 93.) Even as to the ten state Medicaid programs that produced some detailed claims data, there are significant time periods for those states where claims data is not available. Likewise, as to Medicare, the Government does not have or use the pricing arrays from scores of Carriers and time periods necessary to know how, if at all, an AWP for Abbott NDCs actually impacted the median AWPs used in adjudicating Medicare claims. (*Id.* ¶¶ 116, 143.) *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, 491 F. Supp. 2d 20, 99 (D. Mass. 2007) (noting that for multi-source drugs, pricing was "a legal cause of plaintiffs' injury only when reporting a true AWP would have actually shifted the median").

The Government has only itself to blame for the unavailability of this data, having failed to preserve the evidence during the 14 years since the complaint was filed—as set out in more detail in Abbott's separate spoliation motion. (*See* Dkt. No. 6097 at 4, 14-15.) The unavailability of the evidence necessary to prove and quantify this causal link warrants partial summary judgment as to damages on all claims for which the Government does not have or use the underlying data.

The Government cannot use an expert opinion to paper over this glaring deficiency in its case. The Government asked Dr. Duggan to extrapolate data from ten states and a handful of Medicare Carriers to cover the massive gaps in its data, both within the group of states for which some data was used, and across states and Carriers for which no data was used. Abbott has moved to exclude all testimony from Dr. Duggan concerning any aspect of his damages computation that relies upon such extrapolation because, as set out in more detail in that motion (filed herewith), Dr. Duggan's extrapolated "differences" are inconsistent with basic statistical standards, they are subject to clear selection bias, and they are demonstrably unreliable.

Without this expert testimony, the Government has no evidence at all to prove causation and damages for the many allegedly false claims where the Government lacks actual data. *See, e.g.*, *Albert v. Warner-Lambert Co.*, 234 F. Supp. 2d 101, 106-07 (D. Mass. 2002) (excluding expert testimony on damages and granting defendant's motion for summary judgment).[10] And even with the testimony, no reasonable jury could conclude that the Government has proved that the damages were sustained "because of" Abbott's acts. *See* 31 U.S.C. § 3729(a); *see also Daubert*, 509 U.S. at 596; *see, e.g.*, *Miller v. Mandrin Homes, Ltd.*, 305 Fed. App'x. 976, 979-80 (4th Cir. 2009) (concluding that even if expert's conclusions were admissible, they would not defeat summary judgment). Summary judgment on these extrapolated claims is required.

Finally, beyond just the practical impact of the unavailability of data for claims paid by 39 states and numerous Carriers, there is the litigation impact of the Government not having produced at least a representative sample of allegedly false claims when ordered to do so. On December 4, 2008, the Court granted Abbott's motion to compel the Government to produce a "representative sample" of the allegedly false claims at issue. (SOF ¶¶ 170-71.) Due to the great variation in the methods that Medicare Carriers and state Medicaid programs used over time to determine payment amounts for the J-Codes and NDCs at issue, Abbott argued that "the sample of Medicaid claims include an allegedly 'false claim' for each NDC at issue, each year, and each state Medicaid program, and that the sample of Medicare claims include an allegedly 'false claim' for each J-Code at issue, each year, and each Medicare Carrier." (Dkt. No. 5173 at 7; Ex. FJ, Dec. 4, 2008 Hrg. Tr. at 50:16-19 ("[A]ll we're asking for is let's say program by program one a year for each of the drugs, for each of the NDCs at issue, each of the J-codes at issue on the

[10] *See also, e.g.*, *Norfolk Southern Corp. v. Chevron U.S.A., Inc.*, 279 F. Supp. 2d 1250, 1268-79 (M.D. Fl. 2003), *rev'd on other grounds*, 371 F.3d 1285 (11th Cir. 2004); *Dunn v. Sandoz Pharm. Corp.*, 275 F. Supp. 2d 672, 684 (M.D.N.C. 2003).

sides. Give us a sample . . . .").) After hearing Abbott's argument as to what constitutes a "representative sample," Magistrate Bowler ordered the Government to produce false claims "on a sample basis." (Ex. FJ, Dec. 4, 2008 Hrg. Tr. at 51:22-23.) All the Government produced, however, was data (not claims) and only from California, Florida, Illinois, Kentucky, Louisiana, Michigan, Missouri, New Jersey, New York, Ohio, and Wisconsin, the ten states for which their expert actually used detailed claims data. Similarly, for Medicare, the Government produced claims only from those same Carriers for which the Government produced arrays, the tools used by Medicare Carriers to pay based on Medicare's median-based formulas.[11] Because it did not include claims from all states and Carriers, covering the complete time period, the Government did not produce a representative sample as to the missing states, Carriers, and time periods.

The Government has thus forfeited any right to recover damages for the 39 states and numerous Carriers for which it has not produced representative samples, as ordered by the Court. *See* Fed. R. Civ. P. 37(b)(2)(A)(ii) (upon violation of a discovery order, court may "prohibit[] the disobedient party from supporting . . . designated claims"). That the Government's "unjustified failure to respond to [the] discovery order[] was the *cause* of the lack of evidence necessary precisely to determine damages" also requires that summary judgment be granted on damages for those states. *Update Art, Inc. v. Modiin Publ'g, Ltd.*, 843 F.2d 67, 72 (2d Cir. 1988) (affirming Rule 37 sanctions based on defendants' failure to produce evidence on damages, resulting in summary judgment for plaintiffs).

C. The Court Should Grant Summary Judgment As To All Medicaid Claims Reimbursed On The Basis Of An "AWP Proxy" For WAC.

In the Massachusetts AWP case, this Court held that defendants are not liable on those

[11] The Government's production of data rather than claims, as ordered, highlights a further deficiency in the Government's proof. That shortcoming, however, can be dealt with at trial.

claims for which the state used an AWP-proxy, and not WAC (as required in its payment formula), to compute the payment amount. *Mylan Laboratories*, 608 F. Supp. 2d at 134, 147-48 ("Defendants' motion for summary judgment . . . must be granted as to the claims submitted during the periods of time in which they published only AWP and not WAC."). The Government's damage model ignores this precedent.

Many state Medicaid programs used AWP exclusively in determining estimated acquisition cost ("EAC"), one basis for payment under federal regulations. But at least 9 states—Alabama, Florida, Illinois, Maryland, Massachusetts, Missouri, Ohio, Rhode Island, and Texas—included WAC in their payment formula for some portion of the damage period. (SOF ¶ 173.) For significant portions of the damage period, four states defined EAC exclusively in terms of WAC—Alabama (1991-99), Florida (1991-99/2000), Massachusetts (1991-2001), Rhode Island (1995-2001). (*Id*.)

Yet, for the 44 Abbott NDCs at issue in this case, compendia rarely published WACs. Indeed, from 1991 through May 2001, First Databank published WACs for only two NDCs, with relatively minor expenditures. (SOF ¶ 174.) Dr. Duggan, though, did nothing to exclude claims paid based on an AWP-proxy for WAC in his "difference" calculation, nor did he even know how claims in WAC states were paid. (SOF ¶ 121.)

In short, the Government has no evidence that claims paid in WAC states were based on Abbott's conduct or were even false. *See Mylan Laboratories*, 608 F. Supp. 2d at 134, 147-48. Accordingly, the Court should grant summary judgment as to Abbott on all claims for which states utilized an AWP-proxy for unpublished WACs when AWP was not included in the states' reimbursement formula.

D. The Court Should Grant Summary Judgment As To Any Damages Attributable To Ohio Medicaid Claims.

On November 12, 2008, after asserting damages on Ohio Medicaid claims for two and a half years (including in Dr. Duggan's initial report), the Government suddenly announced that it had "made the determination to drop our claim for the federal share of Medicaid damages for Medicaid claims in the state of Ohio for the subject drugs during the time period at issue . . . ." (SOF ¶ 167.) Although the Government did not respond to Abbott's request that it explain why the Government was dropping the Ohio claims (*id.* ¶ 168), it apparently did so after realizing that Ohio's payment methodology provided that the State "shall" base payments on MACs when MACs were established (as they were for the 44 Complaint NDCs throughout the damage period)—regardless of whether an EAC calculation or U&C amount were lower than those MACs.[12] The Court should formally remove these claims by granting Abbott summary judgment as to all Ohio Medicaid claims.

II. THE COURT SHOULD GRANT SUMMARY JUDGMENT ON ANY CLAIMS FOR ACTUAL DAMAGES FOR ALLEGEDLY FALSE CLAIMS PAID AFTER VEN-A-CARE FILED COMPLAINTS NAMING THE DRUGS AT ISSUE.

Next, putting aside liability and civil penalties, all claims for actual damages based on allegedly false claims paid after June 23, 1995 for Vancomycin, saline, and dextrose (the filing date of Ven-A-Care's original complaint), and August 12, 1997 for Abbott's sterile water (the filing date of Ven-A-Care's second amended complaint) should be dismissed for either of two reasons. *First*, the False Claims Act requires a showing of "causation" to recover actual damages. But there can be no causation where the Government, fully advised of the alleged fraud and with complaint in hand, continued to pay claims for *over a decade* before unsealing

[12] This underscores that apparently even the Government recognizes that the Court should not allow recovery of damages for any claims paid based on something other than a compendia-reported price. *See supra* §§ I.A & B.

and litigating the complaint as to Abbott. *Second*, because the Government violated Abbott's Due Process rights by abusing the seal period to conduct one-way discovery against Abbott, while allowing the spoliation of evidence crucial to Abbott's ability to defend itself. As a result, the Court should excise post-complaint damages as an equitable remedy.

A. An Allegedly False Claim Does Not Cause Actual Damages As A Matter Of Law When The Government Pays The Claim While Knowing Of The Fraud.

The False Claims Act distinguishes between civil penalties, on the one hand, and actual damages, on the other. For actual damages, the statute adds a causation element. 31 U.S.C. § 3729(a)(1) (Government may only recover actual damages that the "Government sustains *because of* the act of that person.") (emphasis added). Accordingly, under the statute, the Government cannot recover actual damages for an allegedly false claim unless it can plead and prove damages *caused by* the false claim. *See, e.g.*, *United States ex rel. Schwedt v. Planning Research Corp.*, 59 F.3d 196, 200 (D.C. Cir. 1995).

This simple reading of the plain text of the statute is consistent with "common-law tort causation concepts," to which this Court has previously turned in assessing False Claims Act causation. *United States ex rel. Franklin v. Parke-Davis*, No. Civ.A. 96-11651-PBS, 2003 WL 22048255, at *4 (D. Mass. Aug. 22, 2003); *accord United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006) (citing, with approval, Courts "borrow[ing] traditional principles of tort law to analyze causation for damages under the FCA"). A party generally may not seek to recover damages in tort that it voluntarily elects to suffer. As the court put it in the seminal case of *Thompson v. Libby*, 31 N.W. 52, 53 (Minn. 1886),

> [T]o allow a person who has discovered the fraud while the contract is still wholly executory to go on and execute it, and then sue for the fraud, looks very much like permitting him to speculate upon the fraud of the other party. It is virtually to

allow a man to recover for self-inflicted injuries.[13]

In the FCA context, it is the Government's decision to "accept[] . . . and pay for" a false claim which creates its actual damages. *See United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995) (distinguishing FCA cases where the Government is "induc[ed]. . . to pay out funds" from cases with only statutory penalties). Accordingly, it is only logical that if the Government pays a claim *despite knowing of its alleged falsity*, it cannot say that it was damaged "by reason of" (*i.e.*, "because of") that alleged falsity.

The FCA provides for automatic treble damages, and its damages provisions are therefore punitive in nature. *Vermont Agency of Natural Resources v. United States*, 529 U.S. 765, 784-85 (2000). Accordingly, courts typically apply a proximate causation standard to "narrow, rather than enlarge, the field of actions for which FCA liability may be imposed." *Regence Bluecross Blueshield of Utah*, 472 F.3d at 715 n.17; *see also United States ex rel. Fago v. M&T Mortgage Corp.*, 518 F. Supp. 2d 108, 122 (D.D.C. 2007) ("Plaintiff must go beyond a "but for" showing and demonstrate that the false statements in this case were the proximate cause of the Government's actual damages."). Under this standard, damages must not only be foreseeable, but must also have a sufficiently close causal connection to a defendant's conduct. *See Parke-Davis*, 2003 WL 22048255, at *4-*5. In other words, where the Government knew of allegedly false information, yet made a financial commitment or paid out nonetheless, there can be no

[13] *Accord, e.g.*, *Thor Power Tool Co. v. Weintraub*, 791 F.2d 579, 585 (7th Cir. 1986) ("[g]enerally, a defrauded party cannot recover damages for the period after the victim discovers the fraud"); *Slotkin v. Citizens Cas. Co. of N.Y.*, 614 F.2d 301, 313 (2d Cir. 1979) (noting that "[t]his rule prevents a plaintiff from recovering damages for 'self inflicted' injury"); *Sanitoy, Inc. v. Shapiro*, 705 F. Supp. 152, 156 (S.D.N.Y. 1989) ("Many cases have held that if a plaintiff continues to deal with a defendant after discovering the truth of the defendant's misrepresentations, the plaintiff waives any fraud claim for damages arising subsequent to the discovery.") (collecting authorities).

recovery of actual damages.[14]

For instance, in *United States ex rel. Butler v. Hughes Helicopter Co.*, No. CV 89-5760, 1993 WL 841192 (C.D. Cal. Aug. 25, 1993), *aff'd on other grounds* 71 F.3d 321 (9th Cir. 1995), the court held that, even if the defendant were liable under the FCA, "actual damages (in contrast to civil penalties) could not have been found as a matter of law" where the Government "was aware of the deficiencies" that formed the basis of the FCA suit, yet "nevertheless elected to proceed" and execute its contract with Defendant. *Id.* at *16. In such a situation, the Court held, the "government knew what it was getting . . . and it got what it paid for," and thus there was no "causal connection" between the false statements and payment of the false claim. *Id.*

Likewise, in *United States v. Southland Management Corp.*, 95 F. Supp. 2d 629, 642-43 (S.D. Miss. 2000), *aff'd on other grounds* 326 F.3d 669 (5th Cir. 2003) (en banc), applicable regulations of the Department of Housing and Urban Development conditioned payment of Section 8 housing vouchers on management's certification that its properties were in a "decent, safe, and sanitary" condition. *Id.* at 631. The Government brought an FCA suit against a property management company that falsely made this certification; however, it was established that HUD paid Defendant's vouchers despite knowing about the true condition of the properties and the falsity of the certifications. *Id.* Noting that "a statement or claim can be material, *i.e.*, *capable of* influencing action, without actually inducing reliance or causing damage," the district

[14] *See, e.g., United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991) ("It may be, as the district court observed, that no damages were suffered when officers of the United States knowledgeably decided to proceed with the contract" despite its false claims); *United States ex rel. Herbert v. Nat'l Academy of Sciences*, Civ. A. No. 90-2568, 1992 WL 247587 (D.D.C. Sept. 15, 1992) ("The U.S. consented to [the alleged fraud] at a time when it actually knew of Plaintiff's claim, and was on notice of the Plaintiff's allegations of fraud."); Neal J. Wilson, *The Government Knowledge "Defense" to Civil False Claims Actions*, 24 Pub. Cont. L.J. 43, 61 (1994) ("Where the Government has knowledge of allegedly false or fraudulent information submitted in support of a demand for payment, and yet still makes the payment, there would appear to be a break in the causal link between the false or fraudulent claim and the asserted Government injury. In such a situation, the Government's act of making payments despite knowledge of the defendant's alleged wrongdoing makes it difficult to articulate exactly how the Government has been damaged").

court held "that the Government was not, in fact, damaged by defendants' certifications" when it paid the housing vouchers despite knowing about the false certifications.[15] *Id.* at 642-43.

Here, at a minimum, the United States became aware of the allegedly inflated AWP "spread" for Abbott's Vancomycin, saline, and dextrose by June 23, 1995 (Ven-A-Care's original complaint), and Abbott's sterile water by August 12, 1997 (Ven-A-Care's second amended complaint).[16] (SOF ¶¶ 2-5, 15). Yet the Government continued to pay what it alleges are "false" claims for an *additional six years*, until 2001, allowing treble damages to accumulate—and then kept the case under seal for an *additional four years beyond that*, long after the memories of witnesses had faded and evidence was lost. These self-inflicted damages were not "sustain[ed] because of" the allegedly false claims within the meaning of the FCA. Rather, payments were made with full knowledge of the alleged fraud, and indeed, the very complaint with the FCA allegations in this suit *filed and in hand*. The FCA does not permit actual damages in such a situation; to allow otherwise would "permit plaintiffs who know of the defendant's pattern of activity simply to wait, 'sleeping on their rights,' as the pattern continues and treble damages accumulate, perhaps bringing suit only long after the 'memories of witnesses have faded or evidence is lost.'" *Klehr*, 521 U.S. at 186-88 (declining to interpret treble-damages statute to permit this consequence).

B. The Government Cannot Be Allowed To Recover Post-Complaint Actual Damages Consistent With The Requirements of Due Process.

The Government's excessive delay in unsealing, and the resulting prejudice to Abbott, provide an alternative ground for the Court to bar the Government's recovery of actual damages

[15] The court in *Southland* ultimately found that Defendants were not liable, even for statutory penalties.

[16] In fact, the evidence shows that the Government had actually known about such "spreads" on such products well before Ven-A-Care filed its complaint. (SOF ¶¶ 52-53, 55-57.)

for claims paid after complaints naming the four products at issue were filed. This Court has already recognized that "egregious delay" in the Government's unsealing of a FCA complaint "may be sufficiently prejudicial to trigger Due Process concerns." *In re. Pharm. Industry Avg. Wholesale Price Litig.*, 498 F. Supp. 2d at 399. For while the "Due Process Clause does not create a right to *win* litigation," it emphatically does "create[] a right *not to lose* without a fair opportunity to defend oneself." *Lane Hollow Coal Co. v. Director, Office of Workers' Compensation Programs*, 137 F.3d 799, 807 (4th Cir. 1998). Accordingly, courts have found Due Process violations where, as here, the government's delays prevent defendants from obtaining evidence that may have supported their defenses.

For example, in *Lane Hollow*, the Government did not give notice to defendant of the allegations against it for nearly 17 years, during which time the complainant died. *Id.* at 807. Noting that "such notice could and should have been given" before the complainant's death, the court concluded that the "government's grossly inefficient handling of the matter—and not the random timing of death—denied Lane Hollow the opportunity to examine Lockhart." *Id.* This, the court held, was a "core Due Process violation" which prevented the defendant from having a "fair day in court." *Id.* at 808. The court therefore exercised its equitable power to order that defendant could not be held liable. *Id.*; *accord Consol. Coal Co. v. Borda*, 171 F.3d 175, 183 (4th Cir. 1999) (reaffirming that Due Process is violated where the "government's protracted delay was the direct cause of the [defendant's] inability to gather . . . evidence").

Courts have also found "the analogous issue of pre-indictment delay in criminal prosecutions [to be] both illuminating and persuasive" when determining whether the Government's civil suit is "brought so long after the events in issue that the values of fairness that underlie the Due Process Clause are offended." *DeMichele v. Greenburgh Cent. Sch. Dist.*,

167 F.3d 784, 789-90 (2d Cir. 1999). In the criminal context, the Supreme Court has held that Due Process is violated when the Government's delay is an "attempt to gain an unfair tactical advantage over the defendant or in reckless disregard of its probable prejudicial impact upon the defendant's ability to defend against the charges." *United States v. Eight Thousand Eight Hundred and Fifty Dollars ($8,850) in U.S. Currency*, 461 U.S. 555, 563 (1983) (*citing United States v. Lovasco*, 431 U.S. 783, 796 & n.17 (1977)); *Ezerkis v. Guirbino*, No. 1:05-CV-01208, 2009 WL 500321, at *1 (E.D. Cal. Feb. 26, 2009) (requiring proof that delay was done to "gain an advantage" or in "reckless disregard for prejudice" to show Due Process violation); *Zayas v. Krysevig*, No. 08-556, 2008 WL 2609991, at *4 (E.D. Pa. June 26, 2008) (same). Similarly, in the False Claims Act context, prejudicial delay caused by the United States' one-sided discovery is unfair, because the sealed complaint deprives the defendant of the protections afforded by the statute of limitations. *Cf. United States v. Marion*, 404 U.S. 307, 323-27 (1971) (noting that, in pre-indictment context, statute of limitations is safeguard against excessive investigative delay).

Here, the Government's delay was egregious and prejudiced Abbott. Under the FCA, the default amount of time for the Government to decide whether to intervene is only 60 *days*. 31 U.S.C. § 3730(b)(2). The legislative history of the 1986 FCA amendments confirms Congress's view that this period is "an adequate amount of time" in "the vast majority of cases." S. Rep. 99-345 at 25, *as reprinted in* 1986 U.S.C.C.A.N. 5266, 5290. As suggested by the brevity of the 60-day pre-intervention period—*i.e.*, a period of time shorter than any typical civil discovery schedule—Congress did not intend for the Government to use the seal period in order to engage in full-fledged, one-sided discovery outside the avenues of normal civil litigation. The pre-intervention period was intended merely to allow the Government to "determine both if that suit involves [criminal] matters [it] is already investigating and whether it is in [its] interest to

intervene and take over the civil action." *Id.* The legislative history underscores the point, noting that good cause for extending the seal period "would not be established merely upon a showing that the Government was overburdened," and that the "Government should not, in any way, be allowed to unnecessarily delay lifting of the seal from the civil complaint or processing of the *qui tam* litigation." *Id.* at 24-25, *reprinted in* 1986 U.S.C.C.A.N. at 5289-5290.[17] The Government's delay in this case flouts these established standards in several ways.

First, the time alone here is damning. Measured against the standard 60 days, the *3,920 days* from the filing of Ven-A-Care's complaint to the time that the Government decided to intervene in this case—over 65 times longer than contemplated by statute—is staggering. To place it in perspective, this 11-year delay was longer than both the FCA's general six-year statute of limitations *and* the FCA's 10-year statute of repose. *See* 31 U.S.C. § 3731(b)(1), (2).

Even more damning is the fact that the FCA allows only a *three year* extension of the statute of limitations "after the date when facts material to the right of action are known or reasonably should have been known by the [appropriate] official of the United States." *Id.* § 3731(b)(2). In other words, had the Government obtained knowledge of the purported fraud on its own accord, it would have had only *three years* for a full pre-complaint investigation before the claims would be untimely. Thus, but for the tolling effect of the secret complaints under the FCA, most or all of the allegations Abbott faces would have been rendered untimely well before Abbott even received *notice* that it faced liability.

[17] Indeed, the only example Congress gave of a situation that "would often establish" good cause for an extension was "a pending *criminal* investigation of the allegations contained in the qui tam complaint," reasoning that a public civil filing could "tip off" the targets of criminal investigations. *Id.* Even then, however, Congress "[did] not intend that criminal investigations be considered an automatic bar to proceeding with a civil fraud suit." *Id. A fortiori*, the Government's mere desire to fully investigate the *qui tam* allegations themselves, where no parallel criminal investigation is pending, is not a justifiable reason for keeping a case under seal, thereby depriving a defendant of notice and the ability to prepare a defense of charges.

Second, the Government's *ex parte* motions to extend the seal reflect a cavalier attitude towards its duty to extend the seal only for "good cause." The Government's brief four-page legal memorandum, repeatedly referenced throughout its various motions to extend the seal, flatly misstated the legislative history recounted above, telling the court that "Congress recognized that the Government would frequently require additional time in which to make an informed decision on whether to assume control over the action." (SOF ¶ 62 (citing S. Rep. No. 99-345 at 25, *reprinted in* 1986 U.S.C.C.A.N. at 5290).) Of course, the legislative history says the very opposite—that 60 days is sufficient in "the vast majority of cases." *See supra* at 27-28.

Third, to the extent the Government bothered to argue "good cause" at all, it was disingenuous. The Government told the Court that a "complete investigation is needed in order for the government to make an informed decision whether to intervene," (SOF ¶ 63), but that the investigation was too complex and difficult to be completed within the set deadlines. (*See, e.g.*, *id.* ¶ 63.) That, however, was belied by the Government's own admission, in a May 1997 motion to extend the seal, that "ninety days is sufficient to . . . allow a meaningful assessment of [newly-alleged] Medicaid fraud allegations." (*Id.* ¶ 66.)

Other parts of the Government's filings similarly show that the extensions were not about a complex or difficult pre-intervention investigation; rather, the Government used the seal for its own tactical advantage. The Government admitted that it was using its investigatory powers to "demand [from Abbott] the production of several different categories of documents," including "all documents that discuss or comment upon the policies that Abbott followed in setting of their . . . [AWP prices]." (*Id.* ¶ 64.) Initially, it claimed that it needed this information to assess whether Ven-A-Care's claims were worthwhile. (*Id.* ¶ 63.) But by May 1997, the Government had determined that Ven-A-Care's allegations of fraud were supportable, as it partially unsealed

the complaint so that state Attorneys General could "identify the amount of the losses of that state and to advocate the recovery of that state's losses from the fraud schemes set forth in the Amended Complaint." (*Id.* ¶ 65.)

Thereafter, the Government's seal motions reflected that it was in deep litigation mode, and wished to keep the case sealed for strategic litigation purposes, including a desire to:

- "[P]ress[] defendants" to produce responsive documents," (*id.* ¶ 70);
- "[C]reat[e] an electronic database for storage and review of the thousands of documents," (*id.*), to "share . . . documents" with Medicaid officials and coordinate discovery, (*id.*);
- "[C]onduct . . . witness interviews across the country," (*id.* ¶ 72);
- Retain "teams of accounting and data analysis experts," (*id.* ¶ 78); and
- "[A]ggressively pursue settlement discussions" with the defendants (*id.* ¶ 73).

Year after year, the Government asserted that "the requested extension[s] will permit counsel for the United States to" continue these sorts of activities.[18]

Finally, certainly a party gains a tactical advantage over its opponent when it is able to keep its claims secret for 11 years, and uses its one-sided ability during that time to gather, catalog, and analyze its opponents' documents, obtain fresh witness testimony, and to use the uncertainty of the sealed complaint as an "inducement to settle the case." (*Id.* ¶ 74.) Abbott, of course, had no ability to subpoena Government documents or witnesses during the eleven-year investigation. Abbott had a much shorter, and non-exclusive, period within which to conduct *its* discovery and, as previously outlined to the Court, by the time Abbott was entitled to discovery, witness after witness was unable to remember relevant details on topics related to Abbott's defense. (Dkt. No. 6097 at 18.)

[18] (SOF ¶ 62 (seal extension filings from Apr. 1999, Aug. 1999, Mar. 2000, Jul. 2000, Jan. 2001, Apr. 2001, Jul. 2001, Oct. 2001, Feb. 2002, Jun. 2002, and Oct. 2002).)

As government employees with relevant knowledge left CMS, HHS, and other relevant agencies, their contemporaneous notes, e-mails, and other documents were destroyed. (*Id.* at 11-12.) Again, as set forth in detail in Abbott's spoliation motion (*Id.* at 6-9), the Government disregarded its affirmative legal duty to preserve evidence in connection with this litigation, and did nothing to preserve evidence within its possession or control. It continued to breach this duty even after Abbott and other defendants expressly reminded the Government of its duty to preserve evidence, and asked for relevant evidence to be preserved. (*Id.* at 4.) As a result, significant documents relevant to Abbott's defenses, and evidence critical to determining causation and damages, were lost. (*See id.* at 10-18 (cataloguing lost documents).) The Government's egregious delay itself was thus a "direct cause of [Abbott's] inability to gather" all the relevant evidence for its defense. *Consol. Coal*, 171 F.3d at 183; *$8,850 in U.S. Currency*, 461 U.S. at 563 (government violates Due Process by acting "in reckless disregard of its probable prejudicial impact" on one's "ability to defend against the charges").[19]

* * *

In short, what happened here is not the "good cause" contemplated by the FCA. Even if

[19] The Government cannot avoid the Due Process problems by claiming that the seal extensions were authorized by the transferor court. That argument was rejected in *United States ex rel. Health Outcomes Techs. v. Hallmark Health System, Inc.*, 409 F. Supp. 2d 43 (D. Mass. 2006). There, the Government opposed defendant's challenge to its "procedural bad faith and strategic behavior" in an FCA case, arguing that "every action taken by [it] was approved by the [transferor] court with full knowledge of the applicable facts and, therefore, should be given deference as 'law of the case.'" *Id.* at 51-52. Judge Saylor rejected this argument, holding that the "government's *ex parte* actions will not now be left unchallenged in a court that enjoys the benefit of an adversarial proceeding in order to give deference to judgments made by a court that did not." *Id.* at 52. The same rationale applies here. The motions to extend the seal were likewise *ex parte*; as such, Abbott had no opportunity to rebut the Government's claim to "good cause" or to address the constitutional harms caused by the resulting eleven-year delay. Abbott is entitled to have those issues revisited by this Court in assessing whether Abbott's Due Process rights were violated. *See also, e.g., Platten v. HG Bermuda Exempted Ltd.*, 437 F.3d 118, 129 n. 8 (1st Cir. 2006) (rejecting proposed application of law-of-the-case doctrine to legal determination made in *ex parte* proceeding); *Munro v. Post*, 102 F.2d 686, 688 (2d Cir. 1939) (holding law-of-the-case inapplicable to "an ex parte order"); *cf. In re Disclosure of Grand Jury Material*, 821 F.2d 1290, 1293 n.4 (7th Cir. 1987) (holding that, even where *ex parte* decision led to final judgment, affected party that "was not aware of the government's *ex parte* disclosure motions, and thus had no opportunity to intervene and appeal [the final] decisions," had right to "raise its objections" in an "independent action in equity").

some pre-intervention investigation could be justified, the eleven-year, one-sided investigation of claims having a 10-year statute of repose was manifestly unreasonable. *See United States ex rel. Costa v. Baker & Taylor, Inc.*, 955 F. Supp. 1188, 1191 (N.D. Cal. 1997) ("Congress viewed sixty days as sufficient time to make the intervention decision. Given nine times that long, the Justice Department ought to have been able to make up its mind."); *see also id.* ("maintaining the veil of secrecy" to aid "settlement negotiations . . . clearly falls outside of the rationale for the statutory seal provision"); *Berger v. United States*, 295 U.S. 78, 88 (1935) (noting that a government attorney "is the representative not of an ordinary party to a controversy, but of a sovereignty whose obligation to govern impartially is as compelling as its obligation to govern at all; and whose interest, therefore, . . . is not that it shall win a case, but that justice shall be done"). These facts rise to the level of a Due Process violation.

This Court unquestionably has the power to fashion equitable relief from the Government's violation of Abbott's Due Process rights; indeed, the "power of the federal courts to grant equitable relief for constitutional violations has long been established." *Mitchum v. Hurt*, 73 F.3d 30, 35 (3d Cir. 1995) (Alito, J.); *see also Texaco Puerto Rico, Inc. v. Dept. of Consumer Affairs*, 60 F.3d 867, 878 (1st Cir. 1995) (court has equitable power to remedy the "sovereign's dilatoriness"); *Griffin v. Burns*, 570 F.2d 1065, 1079 (1st Cir. 1978) (affirming equitable remedy for Due Process violation). Here, equity requires that the Government receive no benefit from unfairly keeping this case under seal for 11 years. At a minimum, the Government cannot claim "actual damages" incurred after the complaints naming each drug were filed. As discussed above, the filing of a sealed complaint informed the Government of Abbott's allegedly fraudulent activities, yet the Government continued to pay the claims and incur self-inflicted damages. This inflation of alleged actual damages would not have been possible but for the

misuse of the seal provision. For this reason, too, alleged actual damages after June 23, 1995 for Vancomycin, saline, and dextrose (the filing date of Ven-A-Care's original complaint), and August 12, 1997 for Abbott's sterile water (the filing date of Ven-A-Care's second amended complaint), should be barred.

III. ABBOTT SHOULD BE GRANTED SUMMARY JUDGMENT ON THE GOVERNMENT'S UNJUST ENRICHMENT AND HOME INFUSION CLAIMS.

Apart from Ven-A-Care's original AWP-based FCA claims, the Government is also pressing two entirely different claims, both added for the first time by the Government after unsealing:

- An allegation that Abbott's former Home Infusion Services business directly submitted false claims, first added in a First Amended Complaint filed with a motion for leave to amend on November 7, 2007[20] (SOF ¶ 20, Ex. B ¶¶ 111-38); and
- A common-law unjust enrichment allegation added in the Government's March 17, 2006 complaint-in-intervention (SOF ¶ 18, Ex. Q ¶¶ 108-11).

Abbott is entitled to summary judgment on both, as nearly all of the Government's allegations related to these new claims are time-barred and do not relate back to Ven-A-Care's earlier-filed complaints. *See Rodriguez-Garcia v. Municipality of Caguas*, 354 F.3d 91, 96 (1st Cir. 2004) (affirming grant of summary judgment as to time-barred claims).

A. Summary Judgment Should Be Granted On The Government's New Allegations Relating To Abbott's Former Home Infusion Services Business.

On November 7, 2007, the Government sought leave to inject into this case a series of

[20] The date on which the Government filed its motion for leave is the relevant date for statute of limitations purposes. *See Overton v. Se. Penn. Transp. Auth.*, No. Civ. A. 04-904, 2004 WL 1243666, at *3 (E.D. Pa. June 3, 2004) (measuring statute of limitations from the date that motion for leave to amend was filed); *Turner v. First Wis. Mortg. Trust*, 454 F. Supp. 899, 904-05 (E.D. Wis. 1978) (same). Although the Government attempted to file its First Amended Complaint on June 4, 2007, this Court determined that leave to amend was required. *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, 538 F. Supp. 2d 392, 396 (D. Mass. 2008). Therefore, until the Government filed its motion for leave, the First Amended Complaint was "not properly before the court" and had no legal effect. *See Momand v. Paramount Pictures Distrib. Co.*, 6 F.R.D. 222, 224 (D. Mass. 1946); *see also* 6 Charles Alan Wright, *et al.*, *Federal Practice and Procedure* § 1484.

allegations relating to Abbott's former Home Infusion Services business. Home Infusion Services was a very small business at Abbott that focused on the actual provision of home healthcare to patients—as opposed to Abbott's core business of making and selling pharmaceuticals. Abbott owned and operated three home infusion pharmacies, and it also worked with other healthcare systems (primarily university hospitals and the like) that were involved in alternate site infusion care. For these third-parties, Abbott offered a variety of services ranging from training and education about home infusion, to inventory management, to claims administration. For its work, Abbott received from its clients a negotiated percentage of the amount that the clients were paid by third party payors, including Medicare and Medicaid. Based on a variety of business factors, Abbott decided in 1997 to close Home Infusion Services; Abbott honored its remaining contracts, and shut down this business completely in 2001.

The claims made by the Government in 2007 relating to Home Infusion Services are different, both as a matter of fact and law, from the claims Ven-A-Care initially raised in its under seal *qui tam* complaint in 1995. Particularly in light of the Government's extraordinary delay in raising these claims, they should not be deemed to relate back to Ven-A-Care's 1995 complaint. Rather, for purposes of analyzing the timeliness of the Home Infusion claims, the operative date is November 7, 2007, the date the Government sought leave to add the claims.

Although this Court has ruled that the FCA implicitly permits new FCA claims to relate back under Rule 15(c)(1)(A), it has repeatedly emphasized that relation back under this rule "is limited." *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, 498 F. Supp. 2d at 398; *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 2007 WL 4287572, at *3. If the "government's complaint contains new claims unrelated to those asserted in the original complaint, then the original complaint cannot serve as a proper placeholder" under Rule 15(c)(1)(A). *In re Pharm.*

Industry Avg. Wholesale Price Litig., 498 F. Supp. 2d at 398. That is certainly the case with the Government's new allegations relating to Home Infusion Services.

It is black-letter law that it is not enough to allege that claims are "related" simply because they are part of the same "'broad scheme.'" *In re Pharm. Industry Avg. Wholesale Price Litig.*, MDL No. 1456, 2007 WL 4287572, at *3 (D. Mass. Dec. 6, 2007); *see also In re Bausch & Lomb, Inc. Sec. Litig.*, 941 F. Supp. 1352, 1366 (W.D.N.Y. 1996) (rejecting relation back based on notion that pleadings were part of the "same general scheme"). Instead, where, as here, new claims "expand or modify facts asserted in the earlier pleading," they will not "relate back." *United States ex rel. Health Outcomes Techs. v. Hallmark Health Sys., Inc.*, 409 F. Supp. 2d 43, 53 (D. Mass. 2006). Nor will an amended complaint relate back where it "'attempts to introduce a new legal theory based on facts different from those underlying . . . timely claims.'" *La. Wholesale Drug Co. v. Biovail Corp.*, 437 F. Supp. 2d 79, 86 (D.D.C. 2006), *aff'd by Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857 (D.C. Cir. 2008) (quoting *United States v. Hicks*, 283 F.3d 380, 388 (D.C. Cir. 2002)). Here, both the factual and legal theories at the heart of the Home Infusion claims are conceptually distinct from Ven-A-Care's original allegations.

As to the factual theory, Ven-A-Care's original complaint (and all subsequent complaints through the Government's 2006 complaint-in-intervention) focused on Abbott's conduct as a drug *manufacturer* that (1) reported pricing information to the publishing compendia that was allegedly used by Medicare and Medicaid to set payment rates for healthcare providers and (2) negotiated substantially lower actual sale prices for those products with its customers, such as Ven-A-Care and physicians, so that those customers could reap a sizeable profit "spread" by purchasing from Abbott. (*See, e.g.*, SOF ¶ 2, Ex. A ¶¶ 41-44, 96, 100.) The providers administered the products to patients, and then the providers (not Abbott) submitted the allegedly

"false claims" seeking payment from Medicare and Medicaid in an amount substantially higher than what the provider actually paid to acquire them. (*See, e.g.*, *id.* ¶¶ 96, 100.)

By contrast, the 27 new paragraphs about Abbott's Home Infusion Services business that were added in the November 7, 2007 complaint describe allegedly fraudulent behavior in Abbott's capacity as a *provider* of home healthcare services, with respect to both Abbott and non-Abbott drugs. These claims deal with entirely separate enterprises, through which Abbott provided healthcare-related services and then *directly* submitted claims for payment to Medicare and Medicaid. (*See* SOF ¶ 20, Ex. B at ¶¶ 111-38.) As to the three Home Infusion pharmacies, the Government alleges that Abbott itself "owned and operated its own Home Infusion Pharmacies," (*id.* ¶¶ 111-12), that it "stocked and dispensed Abbott products" as well as non-Abbott products (*id.* ¶ 114; *see also id.* at ¶ 120), that Abbott directly filled patient prescriptions and "billed Medicare and Medicaid for products and services dispensed by the Abbott HI Pharmacies using Abbott's EIN number and Abbott's own Medicare and Medicaid provider codes." (*Id.* ¶ 113.) And as to Abbott's business arrangement with its Home Infusion Services customers, the Government alleges that Abbott had various "home infusion partnerships with various hospitals, care facilities and other medical entities," (*id.* ¶ 122), and that it "dispense[d] the drugs or products from its pharmacy" to partners free of charge (*id.* ¶ 125). For some partners, the Government alleged that Abbott would submit claims to Medicare, Medicaid and other third party payors for drugs, medical devices and medical services on the [partner's] behalf." (*Id.* ¶ 126; *see also id.* ¶¶ 127-29.) The reimbursement was paid to the customer, who would "provide a percentage share to Abbott of its entire collections." (*Id.* ¶ 135.)

These differences show that the 27 additional paragraphs did not merely "add details" to the original complaint. *United States ex rel. Deering v. Physiotherapy Assocs., Inc.*, 601 F. Supp.

2d 368, 376 (D. Mass. 2009). They added operative facts that were "not even suggested in the original complaint." *O'Laughlin v. Nat'l R.R. Passenger Corp.*, 928 F.2d 24, 26 (1st Cir. 1991). Therefore, the new allegations cannot relate back to Ven-A-Care's complaint.[21]

As to the legal theory, the Home Infusion claims implicate not just a different argument, but entirely different statutory language. Ven-A-Care's original complaint (and all subsequent complaints through the Government's complaint-in-intervention) claims that Abbott "caused" false claims to be presented by providers. (SOF ¶ 2, Ex. A ¶¶ 48, 96.) The new allegations, however, are premised on a theory that Abbott *directly* presented claims to the United States. (SOF ¶ 20, Ex. B ¶ 31.) This distinction is apparent on the face of the First Amended Complaint, where even the Government bolded its new allegation basing "its claims on Abbott having **submitted and** caused the submission of false or fraudulent claims to the United States . . . ." (Ex. B at ¶ 2 (emphasis in original).) This new legal theory of liability based on new facts cannot relate back to the distinct theory set forth in the original complaint. *Deering*, 601 F. Supp. 2d at 377; *La. Wholesale Drug Co.*, 437 F. Supp. 2d at 86; *United States ex rel. Ortega v. Columbia Healthcare, Inc.*, 240 F. Supp. 2d 8, 14-15 (D.D.C. 2003).

Because there is no relation back for these Home Infusion Services claims, they are untimely unless they accrued by November 7, 2001—within six years of the date the Government sought leave to add them. 31 U.S.C. § 3731(b). Accordingly, the only potentially timely home infusion claims are from November 7, 2001 forward. Thus, to cut off damages at

[21] *See O'Loughlin*, 928 F.2d at 27 (separate allegations of injury, on different days, due to "unsafe and inadequate working conditions" at the same workplace could not relate back); *Health Outcomes Techs.*, 409 F. Supp. 2d at 45, 53 (D. Mass. 2006) (allegation of miscoding specific procedure did not relate back to claims of miscoding same procedure in a different year); *see also Oja v. U.S. Army Corps of Eng'rs*, 440 F.3d 1122, 1133-34 (9th Cir. 2006) (amendment adding a claim arising from unauthorized disclosure of personal information on a website did not relate back to complaint based on a second, identical disclosure on a different website); *Bausch & Lomb*, 941 F. Supp. at 1366 (no relation back where amended complaint included allegations based on an earlier press release that was not mentioned in the previous complaint and "constitute[d] a separate act of fraud").

November 7, 2001, as the law requires, is essentially to dismiss all of the Home Infusion claims. For as set out above, the Government's own complaint sets its damages cutoff at April 30, 2001, several months before November 7, 2001.[22]

B. Summary Judgment Should Be Granted On The Unjust Enrichment Claims.

As this Court suggested in ruling on Abbott's first motion to dismiss over two years ago, the Government will have to elect its remedy as between its FCA and unjust enrichment claims. *See In re Pharm. Indus. Avg. Wholesale Price Litig.*, 491 F. Supp. 2d 12, 19-20 (D. Mass. 2007) (citing *Massachusetts v. Mylan Labs*., 357 F. Supp. 2d 314, 324 (D. Mass. 2005) (suggesting a need for a government plaintiff in an AWP case to elect only one theory of recovery by the time of trial, where, as here, the providers, not defendant, received alleged overpayments)). There is little to elect, however, since nearly all of the unjust enrichment claim is time-barred.

This Court has held that "28 U.S.C. § 2415(a), which provides a six-year limitations period, controls the government's claim of unjust enrichment." *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 498 F. Supp. 2d at 401 (citing *United States v. Intrados/Int'l Mgmt. Group*, 265 F. Supp. 2d 1, 13-14 (D.D.C. 2002)). Accordingly, the "government cannot recover on a theory of unjust enrichment for claims that accrued" more than six years before the allegations were pled. *Id.* Moreover, as the Court has also recognized, unjust enrichment claims

[22] The Government has been somewhat coy about when its alleged damages stop. Its first complaint said that date was January 2001. (SOF ¶ 18, Ex. Q at ¶ 51.) And its First Amended Complaint specifically identified April 30, 2001 as the end of the fraud for the now-dismissed drug Acyclovir. SOF ¶ 20, Ex. B at ¶¶ 50, 71, 85, 88, 90, 100, 110.) The Government later tried to extend, through motion practice, the cutoff date for all drugs, suggesting that as to unjust enrichment, the statute of limitations "limit[s] the government's unjust enrichment claims" for all drugs "to March 17, 2000 through 2001." (Dkt. No. 4661 at 9.) The Court should hold the Government to its complaints, and not allow it to change course in response to this motion, for it is well-established that "a party's assertion of fact in a pleading is a judicial admission by which it normally is bound throughout the course of the proceeding." *Schott Motorcycle Supply, Inc. v. Am. Honda Motor Co*., 976 F.2d 58, 61 (1st Cir. 1992) (affirming summary judgment for defendant despite plaintiff's attempt to contradict factual assertions in its complaint); *see also Rest. Consulting Servs., Inc. v. Mountzuris*, 253 F. Supp. 2d 45, 53 n.5 (D. Mass. 2003) (concluding at summary judgment that plaintiff was "bound by the . . . assertion of fact that it made in its complaint").

cannot relate back to a sealed FCA *qui tam* complaint. *Id.*

Here, the unjust enrichment claim was added in the Government's complaint-in-intervention filed on March 17, 2006. (SOF ¶ 18, Ex. Q at ¶¶ 108-11.) Under the six-year statute of limitations, with no relation back, any claims accruing before March 17, 2000 are time-barred. That means that the only potentially timely unjust enrichment claims are those accruing from March 17, 2000 through April 30, 2001, the date which the Government alleges that damages ended. *See supra* n.22. All other claims must be dismissed.

IV. ABBOTT SHOULD BE GRANTED SUMMARY JUDGMENT ON ALL FCA CLAIMS THAT ACCRUED PRIOR TO MARCH 17, 2000.

Finally, all FCA claims that accrued prior to March 17, 2000, six years before the Government filed its complaint-in-intervention, are time-barred. 31 U.S.C. § 3731(b). This Court has already recognized that "[i]f the Court did not have jurisdiction over Ven-A-Care's" pleadings, "the government's complaint-in-intervention cannot properly relate back" to them. *In re Pharm. Industry Avg. Wholesale Price Litig*., 498 F. Supp. 2d 389, 399-400 (D. Mass. 2007). And rightly so; a complaint filed in a court that lacks jurisdiction over it is not an adequate placeholder for relation back because it is impossible to relate back to something that, *de jure*, never existed. *See Holloway v. United States*, 60 Fed. Cl. 254, 261, 264 (2004); *In re Eldridge*, 348 B.R. 834, 846 (N.D. Ala. 2006). As set out in detail in Abbott Laboratories, Inc.'s Memorandum In Support Of Motion To Dismiss For Lack Of Subject-Matter Jurisdiction Under The Public Disclosure Bar (filed contemporaneously herewith), this Court never had subject-matter jurisdiction over any of Ven-A-Care's complaints because Ven-A-Care failed to satisfy the jurisdictional prerequisites 31 U.S.C. § 3730(e)(4). Permitting the Government to invoke relation back would thus retroactively extend the jurisdiction of this Court to claims that § 3730(e)(4) prohibited it from entertaining in the first place. That, of course, would improper.

The Government may proceed on its own complaint after Ven-A-Care is dismissed for lack of jurisdiction. *Rockwell Int'l Corp. v. United States*, 549 U.S. 357, 476-77 (2007) ("[A]n action originally brought by a private person, which the Attorney General has joined, becomes an action brought by the Attorney General once the private person has been determined to lack the jurisdictional prerequisites for suit."). But that complaint must stand or fall on its own, with no relation back. That requires that judgment for Abbott be entered on all FCA claims accruing prior to March 17, 2000, six years before the complaint-in-intervention was filed.

CONCLUSION

Rather than waste the time and resources of the parties, the trial judge in the Southern District of Florida, and the jury, this Court should now prune out those claims that the Government cannot support with evidence—despite having three years of discovery in this case, and eleven years of one-sided discovery when the complaint was under seal, to do so. The Court should dismiss:

- All FCA claims for claims paid based on something other than a reported price; claims with insufficient evidentiary causation and damages support; claims paid based on an AWP proxy; and all claims for Ohio Medicaid;
- All FCA damages claims after June 23, 1995 for Vancomycin, saline, and dextrose, and August 12, 1997 for Abbott's sterile water;
- The Government's untimely unjust enrichment claims, and claims relating to Abbott's former Home Infusion Services business in their entirety; and
- All FCA claims accruing prior to March 17, 2000.

Dated: June 26, 2009

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Brian J. Murray, an attorney, hereby certify that I caused a true and correct copy of the foregoing ABBOTT LABORATORIES INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR PARTIAL SUMMARY JUDGMENT to be served on all counsel of record electronically by causing same to be posted via LexisNexis, this 26th day of June, 2009.

/s/ Brian J. Murray
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